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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 582,554	06 28 2000	YOKO TATSUMI	4629-006	8304

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RHODES & MASON  
P O BOX 2974  
GREENSBORO, NC 27402

EXAMINER

PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/582,554

Applicant(s)

TATSUMI ET AL.

Examiner

Elli Peselev

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-12, 14 and 16-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-12, 14 and 16-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- 3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language priority document is not submitted.

- 1) ☐ Information Statement (PTO-152)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-648)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413) Paper No. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other \_\_\_\_\_

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Claims 1-12, 14 and 16-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 is directed to the production of compounds 4,5-dihydroxy-2-pentenal, 4-hydroxy-2-cyclopenten-1-one, 4(9-adeninyl)-2-cyclopenten-1-one, 4(9-guaninyl)-2-cyclopenten-1-one, 2-(3,4-dihydroxy-1-butenyl)-4-(2-formylvinyl)-1,3-dioxolane, 1,5-epoxy-1-hydroxy-3-penten-2-one and the compound of formula [I] by heating pentose, pentose derivatives, compounds containing pentose or compounds containing pentose derivatives. However, it is not clear from the specification or the claims which specific compound is heated in order to prepare the specific compounds claimed. There is a good reason to doubt that a pentose, such as xylose, when heated will produce all the specifically claimed compounds. Since the term "pentose", "pentose derivatives", "compounds containing pentose" and "compounds containing pentose derivatives" encompass a large number of compounds including arabinose, xylose, ribose, lyxose, arabitol, xylitol, ribonucleosides, ribonucleotides, arabinan, xylan etc., it would take an undue amount of experimentation to determine which specific compounds are useful in the preparation of which specific compounds claimed.

Claims 12 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds having an apoptosis-inducing ability, does not reasonably provide enablement for does not reasonably provide

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(claim 26), rheumatism (claim 27), the diseases set forth in claim 27 and viral diseases (claim 29). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no known correlation between a compound having an apoptosis-inducing ability and the treatment of various diseases encompassed by claims 12 and 26-29. Note that the term "cancer" encompasses various diseases such as leukemia, ovarian cancer, malignant brain tumors, having different underlying causes and treatments. The term "viral diseases" encompasses common cold and AIDS. Since applicant has not provided any evidence that the claimed agents are useful for the treatment of various diseases set forth in the claims, there is a good reason to doubt that the claimed agents possess the utility set forth in the claims.

Claims 1-10, and 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method claims are indefinite in that it is not clear from the claims which specific pentoses are used to make which specific final products set forth in the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 12, 14, 27 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Ikariya et al (U.S. Patent No. 6,184,381) or Rosenschein et al (U.S. Patent No. 5,984,882).

Ikariya et al disclose the claimed 4-hydroxy-2-cyclopenten-1-one (column 27, line 1).

Rosenschein et al disclose the claimed N-acetylcysteine and glutathione (column 2, lines 40-53).

Claim 11, 12, 14, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikariya et al (U.S. Patent No. 6,184,381) or Rosenschein et al (U.S. Patent No. 5,984,882).

Rosenschein et al disclose N-acetylcysteine and glutathione useful for inducing apoptosis (column 2, lines 46-53).

The instant claims read on nothing more than a composition containing said compounds in water. Note that an old compound in water is *prima facie* obvious over the compound *per se*.

Applicant's arguments filed May 29, 2003 have been considered but have not been found persuasive. Applicant contends that claim 11 encompasses compounds not disclosed by the cited prior art. This argument has not been found persuasive since claim 11 has been rejected only insofar as it still encompasses an old compound as disclosed by the cited prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is 703-308-4616. The examiner can normally be reached on weekdays 8.30 a.m. - 5.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-